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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,794	07/15/2003	Ian L. Brown	28053/37955A	7883

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EXAMINER

MAIER, LEIGH C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/619,794

Applicant(s)

BROWN ET AL.

Examiner

Leigh C. Maier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-25,36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-25,36 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Restriction***

Applicant's election without traverse of Group II, claims 13-37, in the reply filed on April 14, 2005 is acknowledged. In the response, claims 26-35, as well as non-elected claims 1-12 and 38 were canceled.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-25, 36, and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to compositions comprising at least 2g of amylase resistant starch wherein the amylase resistant starch is present in at least 5% by weight of the total starch content. However, the disclosure does not specify the method by which the amount of amylase resistant starch is measured. See, for example Table 1 of "Megazyme Resistant Starch Assay Procedure." (It is noted that the date of this reference does not qualify it as "prior art," but it compares assays that were known at the time of the invention. See references at page 2.) The data show the variation in RS depending on the particular assay used. Furthermore, it appears that the results of a *given* assay may vary considerably. Compare the data discussed above with Table 2 of ASP et al (Nutr. Res. Rev., 1996). Furthermore, SEIB et al (US 5,855,946) describe

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different results in using different amylases. See Table V. The claims are thus rendered vague and indefinite.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13, 14, 16-19, 21-23, 36, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by BROWN et al (WO 96/08261).

BROWN discloses a composition in the form of animal feedstuff comprising at least 2g of amylase-resistant starch and 2 g of unsaturated fat. See Table 9. It appears to have the weight percentages required by the claims. The reference is silent regarding the particular physical form of this composition. However, the ingredients would suggest a granular form, and the reference also suggests a granular form. See page 7, 4th paragraph.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-20, 22-25, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over BROWN et al (WO 96/08261).

BROWN teaches as set forth above. The composition disclosed in Table 9 does not appear to be in the form of a powdery mixture. However, the reference specifically suggests a general preparation of the resistant starch compositions that comprises pulverizing the mixture into a powder. See the method at pp 14-15. The reference discloses the use of high amylose maize starch but is silent regarding the particular percentage of amylose in the starch that is used. However, the reference expressly suggests the use of starch having an amylose content of 50% w/w or more, particularly 80% w/w or more. See page 7, 1<sup>st</sup> paragraph.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to pulverize the composition disclosed in Table 9 in order to provide a product that would be more easily incorporated into the preparation of other foodstuffs, such as beverages, yogurts, etc. One of ordinary skill would reasonably expect results because the

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reference expressly suggest such action. It would be further obvious to one of ordinary skill to select any of the starches taught in the reference for their art-disclosed utility.

Claims 13, 14, 16-24, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over GREEN et al (US 5,792,754).

GREEN teaches the preparation of fiber-containing compositions comprising 5-120 g of dietary fiber to be administered in the amount totally about 2000 kcal/day. The makeup of the fiber composition is (1) 15-50% non-starch polysaccharides; (2) 15-45% insoluble non-starch polysaccharides; (3) 8-70% of oligosaccharides and/or resistant starch wherein the oligosaccharides may be present at a level of 8-40% and the resistant starch, and the resistant starch may be present at a level of 5-30%. See abstract.

The reference exemplifies a product wherein the combination of oligosaccharides and resistant starch comprises about 50% of the fiber, and these two components are present in the ratio of about 2:1, respectively. See Example 4. The example suggests the use of this fiber mixture for the preparation of a composition additionally containing 30-45% fat of which should be 33-100% polyunsaturated fat. The reference further discusses packaging the prepared products, which may take a variety of forms, such as liquids (that may be in the form of a powder to be reconstituted) and bars. See col 3, beginning line 56, continuing through col 4, line 18.

It is noted that the reference uses Novelose® starch, which is about 33% enzyme-resistant. The reference uses the resistant starch as a “fiber,” so it would be expected that this refers to the enzyme-resistant portion of the starch, as this is what is considered the “fiber.”

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However, it appears that the reference is referring to the total weight percentage of Novelose® *per se*, and not just the “resistant” portion. Because the reference is not clear on this point, the examiner will allow for the most conservative interpretation of the reference, and it will be assumed that only 33% of any Novelose used is “resistant.”

Regarding example 4, the proportions are given in percentages, and a composition giving weights is not disclosed. However, the reference expressly suggests a composition comprising 5-120 g of dietary fiber per 2000 kcal. Therefore, taking the proportions in example 4 and 60 g/2000 kcal, one could determine a typical composition disclosed by the reference. Of the 60 g, about 20 g would be Novelose®, of which would be about 7 g of amylase-resistant starch. (Regardless of the actual weight, the percentage of resistant starch would remain about 33% of the total starch content.) Dividing the total composition into three meal portions still provides compositions having at least 2 g of resistant starch. The total 2000 kcal composition, assuming about 37% fat or about 82 g total, of which would be about 27-82 g of unsaturated fat. (It is also noted that the preferred level of fat is less than this exemplification but would still fall within the recited limits. See col 4, lines 31-49.)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare the recited compositions by relying on the disclosure of GREEN. As demonstrated above, if one of ordinary skill were to take specific information and combine that with amounts squarely within the disclosed ranges, one of ordinary skill would be reasonably expected to arrive at the instant compositions for their art disclosed utility. It would be further obvious to the composition as a powder for reconstitution, as expressly suggested by the reference.

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*Examiner's hours, phone & fax numbers*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

*Leigh C. Maier*

Leigh C. Maier  
Primary Examiner  
May 31, 2005